SUMMARY OF SAFETY AND EFFECTIVENESS
510(k) Summary

K002912 - 2/21/01

Device Name: Vaginal Port Inflatable Speculum

Device to which Equivalence is Claimed:

Welch Allyn Disposable Vaginal Speculum	K941272
Medscand 's Easy-Spec™	K984221

Indication for Use:

Non-sterile Model:

The sterile Vaginal Port is indicated for vaginal exposure in routine or surgical procedures.

Sterile Model:

The non-sterile Vaginal port is indicated for vaginal exposure in non-surgical applications.

Device Description:

The Vaginal Port is a dual-layered soft bodied inflatable device. The Device consists of a distal, central and proximal chamber. All three are connected to an inflation lumen. Upon inflation, a central core opening is created to access the vagina. The Vaginal Port when inserted into the vagina has a low profile and is flexible. Upon inflation, it expands and becomes rigid. The three-chamber central core opening will allow access to the vagina by the user. The device is capable of simultaneous inflation through a single stopcock. The distal chamber is capable of inflation/deflation independent of the central/proximal portion of the product. The body of the chamber membrane may be inflated with warm inflation media for patient comfort.

Summary of Substantial Equivalence:

Sterilis™, Incorporated believes the Vaginal Port is substantially equivalent to the predicate devices. The Vaginal Port shares the same intended use and achieves the same indicated function as the predicate device.

Conclusion:

It is Sterilis' opinion that the Vaginal Port is substantially equivalent to predicate devices and does not raise new concerns regarding safety and efficacy.

197

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2001

Sterilis, Inc.
c/o Mr. Gary G. Frugard
Gary G. Frugard & Associates
23972 Wanigan Way
LAGUNA NIGUEL CA 92677

Re: K002912
Vaginal Port, Inflatable Speculum
Dated: January 11, 2001
Received: January 16, 2001
Regulatory Class: II
21 CFR §884.4530/Procode: 85 HIB

Dear Mr. Frugard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

January 11, 2001

Indications for Use Statement

510(k) Number: K002912

Device Name: Vaginal Port™ Inflatable Speculum

Indications for Use:

The sterile Vaginal Port is indicated for cervical exposure in routine or surgical procedures.
The non-sterile Vaginal Port is indicated for cervical exposure in non-surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter**_____
(Per 21 CFR 801.109)

(Optional Format 1-1-96)

David A. Lagmore
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002912